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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,044	03/16/2005	Petrus Besselink	BES 0009 PA	2774

23368 7590 10/27/2010

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ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
10/27/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/528,044
Filing Date: March 16, 2005
Appellant(s): BESSELINK, PETRUS

John Reed
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 07/27/10 appealing from the Office action mailed 03/24/10.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-74 are pending. Claims 1-6, 8-10, 13, 15-21, 41, 42, 48, 51, 52 and 55-59 are rejected. Claims 7, 11, 12, 14, 22-40, 43-47, 49, 50, 53, 54, 60-74.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the

subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

6,371,064	TSUGITA	04-2002
5,836,962	GIANOTTI	11-1998
5,814,064	DANIEL	09-1998

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-5, 8, 9, 13, 15, 18-21, 41, 42, 48, 51, 52 and 55-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsugita (US 6,371,064) in view of Gianotti (US 5,836,962).

Regarding claim 1 and 48, Tsugita discloses a medical device configured to be disposed within a body lumen, said device comprising a mesh of braided fibers (25).

Tsugita does not disclose that the fibers are reinforcement fibers coupled to a membrane to form a composite structure. However Gianotti discloses a mesh of braided fibers similar to that of Tsugita, where each fiber is a composite structure (2) (C1:L52-53) formed from reinforcement fibers (4) coupled to a membrane (5). Gianotti discusses the advantages of using a composite fiber to increase biocompatibility without compromising necessary stiffness (C1:L29-49) as well as providing the ability to

incorporate contrast medium for better positioning the device (C3:L58-62) and the ability to provide drug delivery (C4:L31-65). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate these composite fibers in place of the fibers used in the filter of Tsugita to achieve the advantages taught by Gianotti. As such, the combination would result in the fibers of Tsugita (25) becoming fibers coupled to a membrane to form the composite structure.

Additionally modified Tsugita discloses: Claims 1, 2, 48, 55: further comprising a frame (22) attached to the fibers (mesh 25) to hold the fibers in a desired shape, said frame comprising a proximal end (111) and a distal end (112); Claim 3 and 48: further comprising an elongated member (30) configured to transport said device to an appropriate location in said body lumen; Claim 4 and 52: wherein said elongated member comprises a guide wire (30) attached to at least one of said frame or said composite structure (Fig. 4c); Claim 5: wherein said proximal end of said frame is remote from said membrane (Fig. 4c); Claim 8: further comprising a plurality of slide rings (111, 112), each of said slide rings connected to opposing ends of said device such that said slide rings are responsive to displacement forces imparted thereto by said guide wire; Claim 9: wherein the reinforcement fibers are directly attached to one of said slide rings and said distal end of said frame; Claim 13: wherein said frame is configured to allow said guide wire to move freely in axial, radial, tangential and rotational directions within said frame when said frame is in an expanded state without influencing the position and shape of said device (C2:L58-63); Claim 15: wherein said frame has elongated struts (181) that define attachment points at said proximal end to

facilitate connection of said frame to said guide wire (Fig. 16a); Claim 18: further comprising a hollow tube (10)advance able into a region at least partially enclosed by said composite structure when said composite structure is in an open state; Claim 19: said guide wire is configured to fit within said hollow tube (C10:L40-55); Claim 20: said tube is configured to perform at least one of a suction, flushing, inspection, measuring, clot-breaking, and retrieval device introduction functions while said tube is advanced into said at least partially enclosed region (angioplasty C10:L45); Claim 21: said hollow tube is dimensioned to serve as a removal sheath for said device; Claim 41: wherein said composite structure is a filter that is expandable into an expanded state, said filter comprising a substantially closed distal end and an open proximal end such that said filter tapers from said proximal end to said distal end (Fig. 16a); Claim 42: further comprising a reservoir (defined by membrane 22) in said filter that extends from said distal end, said reservoir defining a debris storage space; Claim 51: and a plurality of stops (167, 168; C14:L53-57) affixed to said guide wire such that upon contact between one of said stops and one of said first or second rings due to movement of said elongated member, said device moves either into or out of said body lumen.

Regarding claim 55: modified Tsugita teaches first coupled to the membrane and second fibers coupled to the frame (even though all fibers would be the same, some can be chosen to be in the first group and some chosen to be in the second group) and a guidewire (30) coupled to the frame (22) and the composite structure (25) (Fig. 4c); Claim 56: the first fibers are reinforcement fibers; Claim 57: the frame is attached to the composite structure through the reinforcement fibers; Claim 58: the material making up

the first and second fibers is the same; And Claim 59: the reinforcement fibers are discontinuous (since there are multiple fibers) and dispersed throughout said membrane (Fig. 3).

Claims 6, 10, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsugita in view of Gianotti as applied to claims above, and further in view of Daniel (US 5,814,064).

Tsugita modified by Gianotti does not disclose that which is taught by Daniel. Daniel teaches a filter device that comprises pulling fibers (222) connecting said proximal end of said frame to said guide wire (indirectly) to enable said device to be retracted into a removal sheath by a pulling force on said guide wire in order to retrieve said device from said body lumen (C9:L64-C10:L2). The fibers are connected to attachment points by means of attachment holes (220) disposed therein.

As to claim 17, Daniel teaches a fiber connected to attachment points but is silent as to how the fibers are attached. The claimed phrase "by gluing or welding" is being treated as a Product by Process limitation that is that is the fibers are attached by the process of gluing or welding. As set forth in the MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ

964, 966 (Fed. Cir. 1985) (citations omitted) (See MPEP § 2113). Examiner will thus evaluate the product claims without giving much weight to the method of its manufacture.

(10) Response to Argument

Appellant states that the Gianotti reference does not provide the structure of a fiber reinforced membrane. Appellant explains that a membrane is defined as a "thin, soft pliable sheet or layer" and given no special definition in the specification, it is the plain meaning of the claim requirement that must be considered. Appellant states that it is clear that the intention of the claimed composite was to possess a "relatively thin membrane coupled to reinforcement fibers". Appellant argues that Gianotti's concentric reinforced fiber construction does not meet the limitations intended by the plain meaning of the terms. Examiner respectfully disagrees. Gianotti does disclose a membrane (5) coupled to reinforcement fibers (4). The outer layer is "relatively thin" in that Gianotti discloses that the thickness of both the fibers and the outer layer are adjustable based on the user's needs (C6:L46-63). The outer layer is "pliable" in that the composite filaments are used to construct an endoprosthesis for use in the vessels which would necessarily have some flexibility for delivery through the vessels. The outer layer "membrane" can be porous for taking up liquids (C4:L50-65) which further lends itself to being defined as a membrane. Note that the terms "thin" and "pliable" are terms of a relative degree that is given no basis for comparison. For this reason they are considered broad and relatively unlimited.

Examiner agrees that claims in a pending application should be given their broadest reasonable interpretation *consistent with the specification*. This means that the words of the claim must be given their plain meaning *unless the plain meaning is inconsistent with the specification*. In this case, as stated by the appellant, the plain meaning interpretation is not inconsistent with the specification and thus applicable. As explained above, the Gianotti reference meets the limitations as understood by the plain meaning of the term "membrane". It is also true that although the claims are interpreted in light of the specification, *limitations from the specification are not read into the claims*. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Thus one would not look to the specification to determine that "a medical device" is actually disclosed as a filter and so only prior art disclosing a filter is applicable. In the same manner, one would not look to the specification to determine that "a membrane" is disclosed as a filter membrane. "Though understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim limitations that are not part of the claim." *Superguide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875, 69 USPQ2d 1865, 1868 (Fed. Cir. 2004). See also *Liebel-Flarsheim Co. v. Medrad Inc.*, 358 F.3d 898, 906, 69 USPQ2d 1801, 1807 (Fed. Cir. 2004)

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Elizabeth Houston
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Examiner, Art Unit 3731

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